## Policy No. 103.19 - Pharmacy & Therapeutics Review

The BSPH IRB requires review and approval by a representative of the Pharmacy and Therapeutics (P&T) Committee for any use of approved, unlicensed, or unapproved drugs, botanicals, biologics, other related substances (e.g., food additives, food derivatives, vitamins, minerals, extracts, etc.), or complementary and alternative medicines (CAMs) in a research protocol prior to final IRB action on a protocol. This objective will be accomplished by ensuring that IRB FC shall have a member who is also a member of the P&T Committee. When a P&T member for the IRB FC must be absent from a meeting, a P&T Committee alternate may serve as a designated alternate and attend the meeting. In cases where a P&T IRB member or alternate cannot attend a convened meeting, the IRB will postpone review or table applications that include drugs used in clinical investigation until the next meeting when the P&T IRB member can attend.

BSPH IRB X reviews research that qualifies as a minimal risk activity which may be reviewed through an expedited review process. BSPH IRB X may review applications that include a marketed drug only if it obtains a written consult from a P&T/IRB member from IRB FC. The P&T IRB members will provide information to the P&T Committees of the JHM hospitals and affiliates to assure proper communication regarding drug research approved for conduct at the Hospitals.

The review process conducted by the P&T IRB Liaison must include review of issues related to the following:

(a) drug safety, including a review of any REMS or black box warnings ;
(b) drug management;
(c) study design;
(d) IND status;
(e) IDDS review for INDs, and for drugs requested by the P&T representative
(f) informed consent documents; and
(g) any other relevant material.

The IRB will be responsible for reviewing [in accord with the Organization policy 103.6(b),] unanticipated problems involving risk, which may include adverse drug events that occur during a clinical investigation.